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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/710,633	11/08/2000	Stephen B.H. Kent	TSRI 478.0C1	6210

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04/17/2003

THE SCRIPPS RESEARCH INSTITUTE
10550 North Torrey Pines Road
Mail Drop: TPC-8
La Jolla, CA 92037

EXAMINER

RUSSEL, JEFFREY E

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 04/17/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/710,633

Applicant(s)

KENT ET AL.

Examiner

Jeffrey E. Russel

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1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8,10-14,24,26 and 29-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8,10-14,24,26 and 29-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 July 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 17, 2003 has been entered.
2. Applicants are requested to correct the Group Art Unit number in the headings to any papers which are submitted in this application so as to expedite the processing of any such papers.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 11-14, 24, 26, and 29-31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no original disclosure of derivatives of naturally isolatable proteins containing one or more cysteine residues that are not found in the naturally isolatable protein (see claim 24). The original disclosure does not include the concept of altering a naturally-occurring protein's amino acid sequence by replacing amino acids with cysteine residues or by inserting cysteine residues into the amino acid sequence so that a derivative of the naturally-occurring protein can be synthesized by the disclosed method. More generally, and for analogous reasons, there is no original disclosure of derivatives of naturally isolatable proteins containing one or more variant residues that are not found in the naturally isolatable protein (see claim 11).

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5. Claims 24, 26, and 29-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 24 is indefinite because it is not clear what constitutes "an intermediate conformation", and because this limitation may contradict the requirement that "all of the residues of said protein are linked to adjacent residues via an amide bond". Claim 24 does not explicitly state what intermediate conformation the protein is to have. It is possible that Applicants are referring to the β -aminothioester linkage which forms as an intermediate during their synthesis method. However, this is a conformation possessed by an intermediate and which is not possessed by the final protein product. See, e.g., page 1, lines 8-11, of Applicants' specification. If the new claim limitation does not refer to the intermediate β -aminothioester linkage conformation but instead refers to some other type of conformation possessed by the final protein product, it is not clear what this other type of conformation must be.

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 8 and 10-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-45 of U.S. Patent No. 6,326,468. Although the conflicting claims are not identical, they are not patentably distinct from each other because

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the claims of the '468 patent anticipate instant claim 8. The reaction between the C-terminal thioester group and the N-terminal cysteine group in the claimed method of the '468 patent will inherently and spontaneously result in the formation of an amide bond between the respective peptide segments. Note that the instant claims do not exclude the possibility that the first oligopeptide may be bound to a solid phase. With respect to instant claims 10 and 12-14, while the '468 patent does not claim forming a naturally isolatable protein such as a human cytokine, it would have been obvious to one of ordinary skill in the art to synthesize such proteins by the claimed method of the '468 patent because naturally isolatable proteins such as human cytokines are known and useful proteins, because the synthesis method of the '468 patent is applicable to proteins in general, and because it would have been desirable to synthesize such proteins in order to avoid contaminants which may result from extraction or recombinant methods of production.

7. Claims 24, 26, and 29-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamagishi et al (U.S. Patent No. 4,990,455). Yamagishi et al teach human TNF in which residue 145 is replaced with cysteine. Residue 144 is glutamic acid, a non- β -branched amino acid residue. Note that process steps do not impart patentability to product-by-process claims where the product is otherwise anticipated by or obvious over the prior art.

8. Applicant's arguments filed March 17, 2003 have been fully considered but they are not persuasive.

The rejection under 35 U.S.C. 112, first paragraph, concerning the insertion of cysteine residues into naturally isolatable proteins is maintained. Note that claim 24 still requires the insertion of cysteine residues specifically, as opposed to amended claim 11, which recites amino acid variants in general. Applicants' traversal of this rejection did not address this more specific

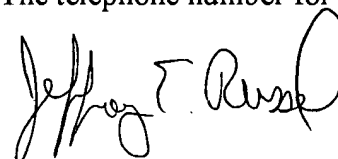
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limitation which remains in claim 24. The rejection continues to be applied against claim 11 and the claims dependent upon it for the reasons of record. The sections of the specification quoted in Applicants' response do not mention amino acid variants as currently claimed. The statement that the invention "raises the exciting prospect" of unrestricted variation of protein covalent structure indicates that the inventor did not have in his possession the claimed invention at the time the application was filed.

The rejection over Yamagishi et al is maintained, pending resolution of the issue under 35 U.S.C. 112, second paragraph, set forth above.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback can be reached at (703) 306-3220. The fax number for Art Unit 1654 for formal communications is (703) 305-3014; for informal communications such as proposed amendments, the fax number (703) 746-5175 can be used. The telephone number for the Technology Center 1 receptionist is (703) 308-0196.



Jeffrey E. Russel
Primary Patent Examiner
Art Unit 1654

JRussel
April 16, 2003